REMARKS

I. AMENDMENTS TO THE APPLICATION

Entry of the amendments to the application is respectfully requested. As detailed below, the amendments introduce no new matter.

The amendments to existing claims are made for clarity and definiteness of the claimed invention. The amendments to claims 1, 15, 42 and 142 should obviate Examiner's below rejections under 35 USC §112 for indefiniteness and incompleteness. Specifically, these claims have been amended to expressly recite that the sequence referenced in the claims as SEQ ID NO 37 is the sequence of EST Accession no. AA098865. Support for this amendment is found in the specification, as previously amended, at page 13 lines 20 to 25 wherein it is stated that the sequences specified by EST Accession no. is TCCGCCTACCTCGGCTACCCCGGGAACCGCTTCGAGCTGGTGGCGCTGATGGCGGAT TCCGTGCTCTCCGACAGCCCCGGCCCCACCTGGGAGNAGTGGTGACGCTCGTGACCT TCGCAGGGACGCTGCT (SEQ ID NO: 37).

Claim 24 is amended to remove reference to a non-elected invention.

Claim 142 is amended to clarify that the isolated or recombinant nucleic acid comprises a polynucleotide sequence of SEQ ID NO: 1. Examiner has properly interpreted this claim in the current Office Action, and Applicants thank the Examiner for pointing out this omission.

Claims 1, 4, 17 and 42 are amended to remove the language "having" and replace it with the language "that is" pursuant to Applicants' discussion with the Examiner and with the Advisory Action of November 10, 2005.

Canceled claims 43 and 44 are being brought into compliance with 37 C.F.R. § 1.121 pursuant to Examiner's Notice of Non-Compliant Amendment dated November 10, 2005.

These amendments should address Examiner's concerns and obviate Examiner's rejections under 35 U.S.C. §112 first paragraph for written description and new matter and under 35 U.S.C. §112 second paragraph for indefiniteness. These amendments add no new matter. Accordingly, entry of these amendments is respectfully requested.

This response is being filed in accordance with recently revised 37 C.F.R. § 1.121, as set forth in 68 F.R. 38611 (June 30, 2003). If the amendment is considered to be not in compliance with recently revised 37 C.F.R. § 1.121, the Examiner is respectfully requested to contact the undersigned at his earliest possible convenience.

II. Incorporation By Reference

Examiner states that the original claims of the current application recited EST Accession no. AA098865. Through amendments Applicants have recited the precise sequence of that Accession no. On page 14 of the Office Action Response dated March 17, 2005, under the sections titled "Amendments to the Application;" Applicants state that the amendments add no new matter. Applicants further state herein that they have inserted material previously incorporated by reference, and thus the amendments to add a recitation of the Accession no. sequence contains no new matter. (37 CFR 1.57(f)). Applicants thank the Examiner for consideration of the above.

III. Rejections Under 35 USC §112, Second Paragraph

Claims 1, 4-28, 42-45, 142-163 have been rejected for, allegedly, being indefinite and failing to particularly point out and distinctly claim the subject matter of the invention. Claims 1, 15, 42, 142 and claims dependant thereon are considered indefinite because it is unclear whether the phrase "which is...SEQ ID NO:37" refers to the isolated polynucleotide or the Accession number. Claim 42 and claims dependent thereon are rejected because the Examiner finds it unclear as to what the term "the nucleic acid" in line 5 of the claim is referring. Claim 142 and its dependent claims have been rejected because the Examiner is unclear whether the isolated polynucleotide "is" SEQ ID NO:1 or whether the isolated polynucleotide "is of" SEQ ID NO:1. Applicants' amendments should obviate these rejections. Nevertheless, the rejections are addressed herein.

Definiteness of a claim under 35 USC §112, second paragraph is a determination of whether the claim is reasonably clear and precise when analyzed in light of: (A) the content

of the application; (B) the teachings of the prior art; and (C) the claim interpretation that one ordinarily skilled in the art would give to the claim. (*In re Moore*, 439 F.2d 1232 (CCPA 1971)).

Claims 1, 15 and 142 have been amended to address and overcome Examiner's rejection. Moreover, the content of the application and an interpretation of these claims in light thereof would clearly indicate to one ordinarily skilled in the art that SEQ ID NO: 1 is distinct from SEQ ID NO: 37. Page 13 lines 20 to 25 states that "EST Accession no. AA098865 is ... (SEQ ID NO: 37)." Page 3 lines 3 to 13 of the application states that "SEQ ID NO: 1 is "distinct from EST Accession no. AA098865." Therefore, the claim language as previously presented was definite and particularly pointed out that the phrase "which is ... SEQ ID NO: 37" refers to the Accession no. Nonetheless, and in order to advance prosecution of this case, Applicants have amended these claims. Applicants respectfully request that the Examiner withdraw this rejection of these claims.

Claim 42 has been amended to clarify the recitation to SEQ ID NO: 37 as being the sequence for EST Accession no. AA098865. Therefore, "the nucleic acid" is properly referring to "[a]n isolated or recombinant nucleic acid...". This current amendment should obviate Examiner's rejection. Applicants respectfully request that the Examiner withdraw this rejection.

Examiner has rejected claims 142-163 because it is unclear whether the isolated polynucleotide sequence "is" or "is of" SEQ ID NO:1, thereby making these claims indefinite. Applicants agree with the Examiner's interpretation of the claim. Applicants' amendment should obviate this rejection. Accordingly, it is respectfully requested that the Examiner withdraw this rejection.

Applicants submit that the rejections under 35 USC §112, Second Paragraph have been addressed, and respectfully request that the Examiner withdraw these rejections and allow the claims.

IV. REJECTION UNDER 35 USC § 112, FIRST PARAGRAPH – NEW MATTER

Claims 1, 4-28, 42-45 and 142-163 have been rejected by the Examiner for, allegedly, failing to comply with the written description requirement. Specifically, Examiner has the following concerns: (a) that the claims recite a polynucleotide having greater than 91.6%

identity to SEQ ID NO: 1; (b) that SEQ ID NO: 37 is added to claim 42; and (c) that the addition of SEQ ID NO: 37 to any claim is not properly incorporated by reference. Examiner has stated that these aspects of the current invention were not adequately described in the specification in such a way that one ordinarily skilled in the art could know that Applicants possessed the invention. Examiner is concluding that because the above information is not described in the specification it is new matter.

Claim 42 has been amended and this amendment has been discussed above. That discussion is equally applicable here. In addition, Applicants have discussed the incorporation by reference issue above. Accordingly, the above amendments and remarks should obviate Examiner's rejection of the claims under sections (b) and (c), above. A discussion of the claims rejection under section (a) follows.

Examiner identifies the claim limitation of having greater than 91.6% identity to the novel polynucleotide of the current invention as lacking written description support in the specification. Examiner states that the specification combined with the knowledge of one skilled in the art leaves the skilled artisan with too much speculation to identify polynucleotides having greater than 91.6% identity with the polynucleotides of the current invention. Examiner states further that at the time the invention was made there was no indication or evidence that Applicants intended or explicitly contemplated sequences with greater than 91.6% identity to SEQ ID NO: 1. Specifically, Examiner is basing this rejection on the lack of a literal recitation of 91.6% identity in the specification. Applicants respectfully traverse Examiner's rejection.

Changes to a numerical range are acceptable if one skilled in the art would consider the range limitations to be inherently supported by the original specification. (See *In re Wertheim*, 541, F.2d 257 (CCPA 1976) wherein the original specification recited a range from 25% to 60% and contained examples having 36% and 50%. An amendment to the specification to recite a range of 35% to 60% held to meet the written description requirements.)

In the current case, there is literally described the following ranges: at least 70%, at least 80%, at least 90%, at least 95% and at least 99%, which includes polypeptides with greater than 91.6% identity to SEQ ID NO.: 1. (See page 30, lines 6-8). "At least" is a literal statement from Applicants indicating that a percentage identity from 90% to 100% is contemplated as part of the invention. There is also the following literal recitation at page 4, line 7 of the specification: "80%, 90%, 95% or more identity to SEQ ID NO:1." Applicants have

again literally expressed that the percentage identity can be any between 90% and 100%. Both of these recitations include the claim range "greater than 91.6% identical." So, Applicants disagree with Examiner's statement that "greater than 91.6% identity" is not literally recited in the specification.

Applicants have also provided more than adequate support for allowing one ordinarily skilled in the art to understand and identify polynucleotides having a percentage identity with SEQ ID NO:1. Various properties and features of the apoptosis inhibitor polypeptides encoded by the claimed polynucleotides are included in the specification. (i.e., that the polypeptides are apoptosis inhibitors and comprise a variety of domains such as BH1-4, a transmembrane domain and dimerization domains.) The limitation of encoding an apoptosis inhibitor is also included in independent claim 1. The ordinarily skilled molecular biologist will consider that "greater than 91.6% identity to SEQ ID NO:1" is well supported by Applicants' original specification.

Moreover, on page 49 lines 12 to 18 there is a discussion of determining sequence identity or homology between polynucleotides by using methods well-known in the art. Thus, Applicants have provided in the specification ample guidance to one ordinarily skilled in the art for determining polynucleotides having a percent identity with SEQ ID NO: 1 falling within the recited range. Applicants have also provided evidence that the claims are intended to encompass polynucleotides with greater than 91.6% identity to SEQ ID NO: 1. Having provided a literal discussion of ranges of sequence identity, a discussion of the properties of these sequences and a discussion of how to make and determine polynucleotides with a percent identity to SEQ ID NO. 1, Applicants, therefore, respectfully submit that this information is not new matter. Nonetheless, and to expedite prosecution of this application, Applicants have amended claims 1, 4 and 17 to recite numerical percent identity and range as literally provided in the specification.

Applicants have addressed Examiner's new matter rejection of claims 1, 4-28, 42-45 and 142-163 under 35 U.S.C. § 112, first paragraph through the above amendments and remarks. Applicants submit that these amendments and remarks overcome the rejection, and respectfully request that the rejection be withdrawn.

V. REJECTION UNDER 35 USC § 112, FIRST PARAGRAPH – WRITTEN DESCRIPTION

Claims 1, 4-10, 12-23, 26-28, 42-45, 76 and 77 have been rejected under 35 U.S.C. § 112, first paragraph for, allegedly, failing to comply with the written description requirement. The Examiner states that the Applicants fail to provide adequate disclosure to an ordinary practitioner skilled in the art of molecular biology to show that Applicants possessed the claimed invention. Examiner states specifically that there is inadequate written description for claims directed towards polynucleotide sequences having 91.6% identity to SEQ ID NO: 1; and that there is inadequate written description for claims directed towards a polynucleotide sequence that produces a polypeptide having 65% identity to SEQ ID NO: 2. Applicants disagree and respectfully traverse this rejection.

According to the Examiner, the claims do not specifically indicate any particular function for the claimed polynucleotide sequences, and thus could contain nucleic acid molecules that are completely unrelated in function. The Examiner holds that the specification fails to attribute any structure-function relationship between the molecules and the modulation of apoptosis. Examiner concludes that for these reasons the specification fails to adequately describe the claimed sequences. The current claim amendments should obviate this rejection. Nonetheless, Applicants herein address Examiner's rejection.

Adequate written description requires a definition of the structures, formulas, chemical names or physical properties of the composition. (*Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1938 (Fed. Cir. 1997)). Moreover, the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1 Written Description" Requirement, 66 F.R. 1099 (January 5, 2001) provides as follows: "An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that Applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." There is no requirement to recite the complete polynucleotide sequence of each molecule within the scope of the claims to satisfy the written description requirement.

Applicants have provided the chemical structures, formulas, chemical names and physical properties of the polynucleotides of SEQ ID NO: 1 and polypeptide sequences of SEQ ID NO: 2. Applicants have similarly discussed many of the domains within SEQ ID NO: 1 and

SEQ ID NO: 2. For example, Applicants have identified and discussed the BH1 domain, BH2 domain, BH3 domain, BH4 domain, transmembrane domain and dimerization domain. These domains are adequately described in the original specification at SEQ ID NOS: 3, 4, 5, 6, 13 and in the drawings. The recitation of those domains provides both structural and functional information. One ordinarily skilled in the art will readily identifying corresponding nucleotides and amino acid residues between the polynucleotides and encoded polypeptides. Further, at page 3 lines 8-10 and page 17, lines 25-29 of the specification it says that the polynucleotides of the invention encode a polypeptide, such as SEQ ID NO:2. The polypeptides of the current invention are specifically recited as apoptosis inhibitors.

There is additionally a description in the specification of Bcl-B mutants wherein deletions or mutations are introduced into the dimerization domain and the effect thereof. (page 52 line 17 to page 53 line 2). At page 15 lines 1-9 the specification says that Bcl-B comprises an amphipathic .alpha.helix. The specification provides the ordinary practitioner more than adequate guidance regarding this .alpha.helix by providing a polypeptide sequence, a corresponding polynucleotide sequence, a reference for molecular modeling and a discussion that the .alpha.helix is useful for forming ion channels or pores in membranes. There is also a description in the specification of Bcl-B mutants wherein the transmembrane domain is deleted and the effects thereof. (page 53 line 12 to page 54 line 13). The specification provides a detailed discussion of the transmembrane domain and its function in localizing the encoded polypeptide to the mitochondria for modulating apoptosis. (e.g., Example 4, pages 51 to 53). The specification also provides a detailed discussion of the dimerization domain useful for homodimerization and heterodimerization and the related function with respect to apoptosis. (e.g., Example 3, page 51) The specification specifically discusses modulation of apoptosis throughout the specification. (e.g., page 4 lines 15-17, page 7 lines 5-23, page 11 lines 9-11, page 14 lines 25-31, page 15 lines 1-9, figures 3-5 as described in the figure legend and the detailed description, and page 39 lines 17-18). On page 3 lines 3-13 of the specification the definition of the nucleic acids provides a range that includes 91.6% and greater identity to SEQ ID NO: 1 and on page 39 lines 17-22 there is provided a definition that the polypeptides can have 65% identity to SEQ ID NO: 2. Contrafy to Examiner's statement at page 15 of the current Office action, Applicants' have adequately identified structural elements and functional domains for the sequences.

Applicants have provided an adequate written description of the polynucleotide sequences recited in the rejected claims. There is no requirement that Applicants provide the complete polynucleotide structure of every molecule within the claims. Applicants have sufficiently detailed relevant identifying characteristics of the claimed molecules thereby providing evidence that applicant was in possession of the claimed invention. Applicants have directed Examiner to many sections of the original specification to provide complete or partial structures, physical properties, chemical properties and functional characteristics of the claimed molecules. It is therefore submitted that the Examiner's 112, first paragraph rejection has been addressed and overcome via the above arguments. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection and allow these claims.

VI. REJECTION UNDER 35 USC § 112, FIRST PARAGRAPH - ENABLEMENT

On pages 17-19 of the current Office Action the Examiner addresses Applicant's prior statements regarding Enablement. Examiner proffers his approach for making a polynucleotide of the current invention having 91.6% identity to SEQ ID NO: 1, and based thereon maintains his enablement rejection as being unduly burdensome. Thus, claims 1-10, 12-23, 26-28, 42-45, and 76-77 were rejected. Applicants submit that the current claim amendments should obviate this rejection. Nonetheless, Applicants herein address Examiner's rejection.

The specification need not recite details of the claimed invention where one of ordinary skill in the art would consider these details obvious or well known in the art. (*In re Skirvan*, 427 F.2d 801, 166 U.S.P.Q. 85 (C.C.P.A. 1970)). The *Wands* factors for accessing enablement of an invention are: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented: (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. (*In re Wands*, 858 F.2d 731, 8 U.S.P.Q. 2d 1400 (Fed. Cir. 1988)).

Examiner's discussion regarding enablement is in view of the written description rejection. (See page 18 first full paragraph in the current Office Action). It is therefore submitted that Applicants' above discussion of the written description rejection should overcome this rejection as well.

Applicants have disclosed polynucleotide and polypeptide sequences that have certain structural and functional properties. These properties are disclosed and discussed in the specification. Also incorporated into the specification are a variety of protocols, laboratory manuals and scientific journal articles relating to the current invention and giving guidance as to the invention. The specification also provides working examples using the claimed native sequences, as well as mutations, deletions, fusions, chimerics and recombinants thereof. Reading the claims in light of the specification, it is clear that the specification provides sufficient guidance and examples regarding the sequences of the claims to enable one of ordinary skill in the art to make and use the claimed invention. The specification also sufficiently discusses the nature of the invention, including intracellular function and the effect mutations and deletions have thereon. The specification provides a thorough discussion of the prior art, and where in the prior art this invention fits. Reading the claims in light of the specification it is clear that the claims well defined regarding the nature of the invention. One ordinarily skilled in the art of molecular biology, therefore, will know how to make and use the invention as claimed. Thus, enablement is well provided. (See *In re Wands*).

Addressing Examiner's methodology for substituting base pairs in a polypeptide, Applicants respectfully submit that (A) quantity alone is not undue experimentation and (B) one ordinarily skilled in the art will not go about making substitutions to a polypeptide by employing this factorial-based methodology. Rather, one ordinarily skilled in the art will employ a more practical approach by using the knowledge of the current invention with the guidance of any of the well-known techniques and methodologies for generating polynucleotide and polypeptide sequences having substitutions. The structural and functional limitations of the invention have been discussed in this response and/or in the specification. Even if Applicant were to accept Examiner's argument that one ordinarily skilled in the art would employ Examiner's recited methodology, it is well understood that a considerable amount of experimentation is permissible if it is routine. (*In re Wands*). Substituting nucleotide and amino acid residues into a polynucleotide or polypeptide sequence is a routine practice that is well known by those skilled in the art.

The quantity of experimentation required is not excessive in view of the subject matter. As indicated above, methods for the synthesis and comparison of nucleic acid sequences are well understood in the art. Moreover, and as discussed above, the specification teaches the

structures and functions of the invention polynucleotides and polypeptides. When these methods are combined with the teachings of the specification, there is little experimentation to be carried out by one of ordinary skill in the art. What experimentation is required is routine in view of the well-understood nature of the methods.

It is submitted that the current specification provides sufficient guidance as to the invention, both structurally and functionally. The specification also directs the ordinary practitioner to numerous sources for understanding the invention and the methodologies employed therewith. Moreover, one ordinarily skilled in the art of molecular biology will have a substantial understanding of these and other methodologies. Reading the claims in light of the specification provides adequate definition to these claims, allowing one of ordinary skill in the art to make and use the claimed invention without undue experimentation. Applicants therefore respectfully submit that the invention of the current claims is enabled and ask that the Examiner withdraw this rejection.

VII. REJECTION UNDER 35 USC § 102(b)

Claims 1, 4-28, 76, 77 and 142-163 have been rejected by Examiner as, allegedly, being anticipated by WO 00/00506 to Kato et al (hereinafter "KATO"). Examiner states that a portion of the KATO SEQ ID NO: 23 is 100% identical to a portion of the polynucleotides claimed in the current application. It is further stated that KATO teaches sense and antisense probes that hybridize to related sequences under any conditions, and thus would necessarily hybridize with SEQ ID NO: 1 of the current invention. These probes can be attached to a gene chip. Finally, Examiner states that KATO's SEQ ID NO: 23 can be inserted into a vector, expressed by a promoter and transformed into a cell line. Examiner, therefore, believes that KATO anticipates the current invention. Applicants respectfully disagree.

KATO's SEQ ID NO: 23

Examiner relies on only a part of SEQ ID NO: 23 from KATO, namely nucleotides 1-700 of a total 1168 residues. Examiner then finds that this partial sequence shares identity with a part of SEQ ID NO: 1 in the current application, namely nucleotides 74-774 of a total of 887 residues. It is on those grounds that Examiner makes his anticipation rejection, claiming 100% sequence identity between the sequences. Examiner expressly recognizes that

the sequence disclosed by KATO is not the sequence of the current polynucleotides. Examiner's reasoning behind this rejection equates to rejecting all polynucleotide sequences having an ATG start codon as being anticipated by the first disclosure of a polynucleotide sequence having the ATG start codon because on that level one can find 100% identity. Such is an incorrect application of 35 USC 102 (b) that would cripple if not paralyze the patenting of sequences.

To qualify as being anticipatory, a reference shall disclose all of the elements and limitation of the claim such that there is no difference between the claimed invention and the disclosed reference. (See e.g., *Magnesystems Inc. v. Nikken Inc.*, 34 U.S.P.Q.2d 1112, 1119 (1994)). Disclosure of genus does not necessarily anticipate a species or make the species obvious if the genus is large and there is no guidance or teaching that points to the species. (See *In re Jones*, 21 U.S.P.Q. 2d 1941 (Fed. Cir. 1992) and *In re Baird*, 29 U.S.P.Q. 2d 1550 (Fed. Cir. 1994)).

KATO is teaching a method for identifying polynucleotides encoding hydrophobic domains. (See KATO page 1 lines 5-22, page 3 lines 17-21 and page 52 lines 29-30). In the background section of KATO, it is further stated that membrane protein having hydrophobic domains are well known in the art. (See page 2 line 12 to page 3 line 14 of KATO). KATO goes on to state that the prior art methods of isolation and identification of a hydrophobic domain bearing molecule focuses on the gene, whereas KATO's method focuses on isolation and purification from a cDNA approach. KATO then identifies a number of polynucleotide sequences having this domain. Some of the polynucleotides (and encoded polypeptides) discussed by KATO are known and some remain unidentified. For example, KATO discusses in the clone examples on pages 40-52 sequences coding FAR-1, NR-13 and Yeast Hypothetical Protein, all of which are previously known. KATO identifies about 10 specific and allegedly unknown polynucleotides, one of which is SEQ ID NO: 23. The intracellular role of SEQ ID NO: 23 is not discussed. Thus, KATO has used an allegedly novel method for identifying specific cDNA molecules bearing a hydrophobic domain. KATO has not, by his own admission, discovered a genus of hydrophobic domain bearing molecules. Rather, KATO has identified specific molecules, one of which is SEQ ID NO: 23. It is notable that KATO did not identify Applicants' polynucleotide sequence despite a massive screening of the human cDNA bank. This fact is admitted by Examiner who is relying on sub-sequences to support his rejection sequence identity between the molecules. KATO's failure to identify Applicants' polynucleotide

sequence following such a massive screening speaks volumes about KATO's molecule not being Applicants' molecule. A further discussion follows.

SEQ ID NO: 23 does not teach residues 1-887 of the claimed polynucleotide. Neither does SEQ ID NO: 23 have 91.6% or greater identity to residues 1-887 of the claimed polynucleotides. The structure of SEQ ID NO: 23 is substantially distinct from Applicants' in that it has 1167 total residues, a 6-bp 5' non-translated region, a 585-bp ORF and a 577-bp 3' non-translated region. Furthermore, KATO does not teach a polynucleotide that targets the mitochondria, that forms a homodimer, that forms a heterodimer with BAX, Bcl-X.sub.L, Bcl-2 or Bcl-B, that modulates apoptosis is any way, or that effects DNA fragmentation in any way. In fact, SEQ ID NO: 23 could not express a polypeptide that forms a homodimer with Bcl-B, as does Applicants' invention, because SEQ ID NO: 23 is not Bcl-B. It is well settled that "[f]rom the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing." (*In re Papesch*, 137 U.S.P.Q. 43 (C.C.P.A. 1963)). It is apparent that SEQ ID NO: 23 teaches neither the structure nor the properties of the polynucleotides claimed by Applicants. There is nothing in the KATO reference that points to the selection of nucleotides 1-700 out of a total of 1167 residues. Why select those particular residues rather than selecting 101-800 or 201-900, neither of which correspond to applicant's claimed sequence? The set of possible sub-sequences of the KATO SEQ ID NO" 23 represents a large genus and there is no guidance as to the selection of the claimed sequences.

As such, KATO is not an anticipatory reference, and Applicants respectfully request to Examiner that this rejection be withdrawn.

Sense and Anti-Sense Probes

Examiner has further stated in support of his 102 (b) rejection that KATO teaches cDNA sense and anti-sense probes for gene diagnosis: the gene in KATO being SEQ ID NO: 23. Examiner states that, absent any stringency constraints for hybridization conditions, SEQ ID: 23 and its sense and antisense cDNA probes will hybridize with SEQ ID NO: 1. Examiner fails to state which claims the above discussion is directed towards. Applicants assume that the rejection is of claim 15 and claims dependent thereon.

Claim 15 and its dependent claims disclose the limitation that the conditions must be stringent. Applicants' specification discloses directly and by incorporation protocols and

references for achieving such stringent conditions with respect to the current invention. Thus, Applicants are claiming probes that hybridize under stringent conditions.

As discussed above, KATO does not teach SEQ ID NO: 1. Additionally, KATO does not teach a probe that will hybridize to Applicants' sequences under stringent conditions. Moreover, KATO discusses generating DNA fragments to be utilized as probes for SEQ ID NO: 23, which is a distinct molecule. KATO does not describe any particular probe he would envision making. Examiner has failed to point to any teaching by KATO for making probes that will bind to Applicants' claimed sequence under stringent conditions. Moreover, Examiner has failed to direct Applicants to a teaching by KATO for making probes that will hybridize under stringent conditions with nucleotide residues 1-73 or 775-887 of Applicants' sequences. Rather, Examiner has admitted that KATO fails to teach these sequences, and thus has failed to teach all elements of the claim. (*Magnesystems, Inc.*). It is the identical invention that must be shown, and KATO cannot meet that standard. Applicants request that the Examiner withdraw this rejection.

Gene Chips and Recombinant Systems

Finally, Examiner stated that KATO anticipates a gene chip comprising SEQ ID NO:1 and an expression vector comprising SEQ ID NO: 1 as well as transgenic cells. Again, Examiner has failed to point to which claims these remarks address. Nonetheless, Applicants have addressed above the differences between KATO and the current application. Regardless of whether Examiner is of the opinion that it is the entire polynucleotide sequences or fragments thereof that are used for the Gene Chips and Recombinant Systems, KATO cannot anticipate these claims because KATO fails to teach the current polynucleotide sequences.

Conclusion Regarding Anticipation by KATO

Applicants respectfully submit that KATO fails to teach the invention of the current claims. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 102 in light of KATO, and allow the claims.

VI. Conclusion

In view of the foregoing arguments, Applicants submit that claims 1-28, 42, 45, 76-77 and 142-163 satisfy the requirements of 35 USC §§ 112 1st paragraph and 102(b).

Accordingly, Applicants respectfully request reconsideration and withdrawal of these rejections and request that the claims be allowed.

The deadline for response to this final Office Action has been previously extended to December 17, 2005 by the filing of a three-month Request for Extension of Time Under 37 C.F.R. § 1.136(a) together with a response. Therefore, this response is being filed in a timely manner.

Respectfully submitted,

Date: December 12, 2005
(Monday)

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